REMARKS

Claims 10-21 are pending. By this Amendment, no claims are cancelled, no claims are amended and no new claims are added.

Claim Rejections – 35 U.S.C. § 103

Claims 10 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,911,042 to Weadock in view of U.S. Patent No. 5,897,572 to Schulsinger et al. Applicant respectfully traverses the rejections.

Neither Weadock nor Schulsinger et al. disclose or suggest "a series of transfixion pins ... radially encircling the cylinder" as recited in claims 10 and 17 in combination with the other limitations of the claims. Rather, Weadock discloses the use of an "anastomotic coupler 20 which includes a tubularly shaped structure 22 consisting of cells 24 which allow for radial expansion from a compliant annular body." Col. 5, lines 21-24. "[A]xially and outwardly bent staples 28, 30" are attached to the opposite ends of the structure. Col. 5, lines 30-33. As seen in Figures 2 through 4 of Weadock, the individual axis of the staples is positioned along the *longitudinal axis* of the body structure, and therefore, by definition, cannot *radially encircle* the body structure. Schulsinger et al. is cited for disclosing a microsurgical needle portion having a circular cross section extending to a trihedral-shaped end portion. Schulsinger et al. does not make up for the deficiencies of Weadock described above.

Secondly, neither Weadock nor Schulsinger et al. disclose or suggest "a mesh cylinder capable of radial expansion between a stable minimal-diameter configuration and a final after-expansion configuration that is also stable" as recited in combination with the other limitations of claims 10 and 17. Rather, Weadock discloses an auto-expandable structure, the construction of which is "constituted of a shape memory metal or alloy material." Col. 5, lines 24-26. The structure forms "a compliant annular body" upon radial expansion. *Id.* Unlike the present

invention, the auto-expandable body structure of Weadock retracts to its initial diameter as soon as the cause of its radial expansion has been removed, i.e. the prosthesis. Again, Schulsinger et al. does not make up for the deficiencies of Weadock described above.

Further, neither Weadock nor Schulsinger et al. disclose nor suggest "a mesh sleeve deformable by use of a balloon catheter" as recited in combination with the other limitations of claim 10. Rather, Weadock discloses the use of a prosthesis delivery device having a "syringe-like or catheter member." *See* Col. 5, lines 50-62 and Figure 4. There is no mention anywhere in Weadock of a *balloon* catheter to expand the sleeve. Again, Schulsinger et al. does not make up for the deficiencies of Weadock described above.

Finally, claim 10 and 17 recite, in part, that "the transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion...." The Office Action states at page 4 that "Schulsinger discloses (see Figs. 1 and 7) a needle having a circular portion extending to a trihedral-shaped end portion thereby reducing trauma to the tissue being penetrated as that cutting edges 16 creates a cleaner incision with less tearing of the tissue (see col. 2, lines 25-28)." However, Schulsinger et al. does not disclose or suggest that "hemostasis is achieved at transfixion sites in the wall of the body duct created by the transfixion pins" as claimed in claims 10 and 17 of the present invention. The suturing needle of Schulsinger does not stay in the wound it creates at all. Rather, Schulsinger teaches the use of two independent means: a first being the needle for cutting the tissue to create a passage, and a second being the suture material for connecting. Although the needle profile may enable penetration of the tissue, the needle does not remain in the tissue after penetration. The tissue is sutured after the needle penetration with a suture. Hemostasis is achieved in Schulsinger, if at all, by the suturing thread and not the suturing needle. On the other hand, in the present invention the circular base of the transfixion pin fills the void in the tissue, acting as a "closure" which enables the transfixion pins to create a tight, safe, secure link over time.

Therefore, independent claims 10 and 17 are allowable because a *prima facie* case of obviousness has not been made. All claim limitations have not been considered in judging patentability per MPEP § 2143.03.

Claims 11-13 and 21 stand rejected under § 103(a) as being unpatentable over Weadock in view of Schulsinger et al. and further in view of U.S. Patent No. 5,397,355 to Marin et al. Marin et al. does not make up for the deficiencies of Weadock and Schulsinger et al. as discussed above regarding claim 10. Claims 11-13 and 21 depend on claim 10 and are allowable for at least the same reasons claim 10 is allowable.

Claims 14-15 and 21 stand rejected under § 103(a) as being unpatentable over Weadock in view of Schulsinger et al. and Marin et al., further in view of U.S. Patent No. 7,022,131 to Derowe et al. Derowe et al. does not make up for the deficiencies of Weadock, Schulsinger et al., and Marin et al. as discussed above regarding claim 10. Claims 14-15 and 21 depend on claim 10 and are allowable for at least the same reasons claim 10 is allowable.

Claim 16 stands rejected under § 103(a) as being unpatentable over Weadock in view of Schulsinger et al. and Marin et al., and further in view of U.S. Publication No. 2003/0120338 to Chobotov et al. Chobotov et al. does not make up for the deficiencies of Weadock, Schulsinger et al., and Marin et al. as discussed above regarding claim 10. Claim 16 depends from claim 10 and is allowable for at least the same reasons claim 10 is allowable.

Claims 19-20 stand rejected under § 103(a) as being unpatentable over Weadock in view of Schulsinger et al., Marin et al. and Chobotov et al., and further in view of U.S. Patent No. 6,241,741 to Duhaylongsod et al. Duhaylongsod et al. does not make up for the deficiencies of Weadock, Schulsinger et al. Marin et al. as discussed above regarding claim 10. Claims 19-20 depend from claim 10 and are allowable for at least the same reasons claim 10 is allowable.

Claim 18 is rejected under § 103(a) as being unpatentable over U.S. Patent No. 5,941,908 to Goldsteen et al. in view of Weadock, further in view of Schulsinger et al., and further in view of Derowe et al. Applicant respectfully traverses the rejection.

Goldsteen et al. does not disclose or suggest "setting in place a first connecting device ...comprising: a mesh sleeve capable of radial expansion between a stable minimal-diameter configuration and a final after-expansion configuration that is also stable..." as recited in claim 18 in combination with the other limitations of the claim. Rather, Goldsteen et al. discloses a radially enlargeable connector structure that is "an elastic, annular structure which is resiliently biased to return to a radially enlarged size...[T]he initial radial compression of each connector structure 30 is maintained by a clip structure 50 on that connector structure." Col. 2, lines 49-61. Therefore, Goldsteen et al. teaches away from the stable minimal-diameter configuration of the mesh sleeve of the present invention.

Further, Goldsteen et al. does not disclose or suggest "a series of transfixion pins on each end of the sleeve, the transfixion pins being of a length sufficient to pass entirely through a wall of the body duct, and adapted to transfix the portion of the intubed ends of the body duct and the prosthesis surrounding the sleeve" as recited in claim 18 in combination with the other limitations of the claim. Rather, Goldsteen et al. discloses tissue-piercing structures 36 of the connector structures 30 which radially penetrate the adjacent body tissue structure 10. Col. 3, lines 44-52. The tissue piercing structures may be barbed to substantially prevent them from coming out of the tissue they have pierced. *Id.* The disclosure of Goldsteen et al. teaches way from the present invention, and would encourage one of ordinary skill in the art to prevent the tissue-piercing structures from coming out of the tissue. This would not facilitate hemostasis.

Finally, Goldsteen et al. does not disclose or suggest "intubing a first end of the prosthesis in an extremity of a first body duct; setting in place a first connecting device by introducing an inflatable balloon catheter into the prosthesis through an end of the prosthesis, ...

[and] intubing a second end of the prosthesis in a second body duct" as recited in claim 18 in combination with the other limitations of the claims. On the contrary, Goldsteen et al. teaches to first insert each axial end of the graft into the body tissue tubing (col. 2, lines 55-58) and then to introduce balloons initially non-inflated into apertures made in the graft. After removing the balloons, these apertures are closed by tightening and securing purse string sutures. Col. 4, lines 40-45. The Office Action, at page 9, states that "[d]ue to lack of criticality in the specification about inserting the inflatable balloon catheter into the prosthesis through an end of the prosthesis was shown to solve no particular problem, serve no particular purpose, and provide no additional benefit as opposed to inserting the catheter balloon into the prosthesis through an orifice on the prosthesis." Applicant respectfully disagrees. In the present invention, the number of orifices made in the prosthesis in order to introduce the catheters is reduced, thereby reducing the chances of a weakened prosthesis. Moreover, required operating times can be reduced since there are less orifices to close, enabling a potential reduction in mortality risk.

Goldsteen et al. teaches away from the present invention in multiple instances, and therefore the combination of Goldsteen et al. with the other cited references as set forth in the Office Action is improper per MPEP § 2145(X)(D)(2). Therefore, claim 18 is allowable.

Lack of Criticality

The Office Action states on page 5, with respect to claim 13, "due to lack of criticality in the specification, expanding the sleeve to a final diameter which is greater than twice its initial diameter was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to expanding the sleeve to twice the diameter or just under twice the diameter." The Office Action also states on page 6, with respect to claim 14, "[d]ue to lack of criticality in the specification, the transfixion pins on each end of the sleeve are straight, and wherein the intermediate transfixion pins are slightly curved was shown to solve no particular

problem, serve no particular purpose and provide no additional benefit as opposed to the modified design of Weadock." Finally, the Office Action states on page 9, with respect to claim 18 as discussed above, "[d]ue to lack of criticality in the specification about inserting the inflatable balloon catheter into the prosthesis through an end of the prosthesis was shown to solve no particular problem, serve no particular purpose, and provide no additional benefit as opposed to inserting the catheter balloon into the prosthesis through an orifice on the prosthesis." The Office Action cites no legal authority for this assertion. Applicant respectfully disagrees with these statements. Nowhere has the Applicant indicated that these or any aspects of the invention lack criticality.

Second, the Board of Patent Appeals and Interferences has addressed the question of "lack of criticality." *Ex parte Michael J. Erland*, Appeal No. 1998-2864, slip op. In that case, the Examiner had rejected a claim limitation stating that it "lacks criticality." *Id.* at 13. The Board wrote that "we will not sustain the rejection of the claims under 35 U.S.C. §103(a) because the Examiner may not dismiss an explicit claim limitation by stating that it 'lacks criticality.'" *Id.* The Board further stated "in any event, lack of criticality is not a measure of the obviousness of the claim subject matter." *Id.* at 14. Thus, "lack of criticality" does not support a rejection for obviousness under §103(a).

The Board again addressed a rejection for "lack of criticality" in *ex parte* Roger Massey. Appeal No. 2003-1660, slip op. at 6. The Board stated "[i]t is not enough to merely allege that something is 'well known,' is an 'obvious matter of design choice,' or 'lacks criticality.'" The Board then cited *In re Lee,* which indicates "[t]he factual inquiry whether to combine the references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions and cannot be dispensed with." 277 F.3d 1338, 1343 (Fed. Cir. 2002).

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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